

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10159

Bowman-Braun Pharmaceutical

Sodium Fluoride Tablets

Major Deficiencies

1. Production Control Deficiency

a. Failure to record of theoretical yield against actual yield and actual yield at various stages of processing.

b. Failure to maintain equipment used for manufacture in a clean and orderly manner to exclude the drug from contamination from previous and current production that might affect the safety, identity, strength, quality or purity of the drug. Examples are:

Tape on tablet filler, counting machine filling spout and other associated parts had accumulation of caked material and the presence of powder of a previous run.

Coating of pink dust on the structural braces of exhaust system and dust and caked material on outside surfaces of coating pans.

Presence of various colored tablets behind tape protector attached to drive of tablet sifter.

c. Uncovered vessel during manufacturing process creates the potential for cross contamination.

2. Laboratory Control Deficiency

Incomplete testing of components and finished product.

Incomplete laboratory records.

3. Lack of a stability testing program.

No data available to determine minimum shelf life of finished product.

4. Inadequate calibration program of test equipment(gages, seals, thermometers).

5. Box of rat poison on same shelf side by side with cans of Aspirin.

6. Inadequate dust control system.

Miscellaneous equipment in mixing area, wall clocks, air conditioner, mixers were dusty.